States and Localities

- 1. California: Drivers drunk on kava new target for police
- 2. Connecticut: State tracking who needs flu shot, files price- ongoing suit
- 3. North Carolina: State: Flu shots only for people at high-risk

National

- 4. Flu shot shortage vexes state officials
- 5. Government scrambling to bring flu vaccine into U.S., antivirals at the ready
- 6. Growing danger: Drugged driving; Movement afoot to pass laws
- 7. Postexposure prophylaxis, isolation, and quarantine to control measles

International

- 8. Canada's vaccine plan may be model for U.S.
- 9. Influenza vaccine supply and international law

Briefly Noted

California price gouging \cdot California fluoridation \cdot Illinois vaccine import \cdot Iowa meth lab plan \cdot Minnesota medical errors \cdot Missouri influenza order \cdot New York tobacco lawsuit \cdot Texas price gouging \cdot Federal flu protection act \cdot National vaccine allocation \cdot 2005 Chiron flu vaccine production \cdot Chiron draft news release \cdot National synthetic drugs action plan \cdot Officials differ on flu crisis

Ouotation of the Week



"Drivers drunk on kava new target for police, DUI conviction spurs prosecutors" San Jose Mercury News (10/25/04) Jessica Portner http://www.mercurynews.com/mld/mercurynews/news/10009050.htm

Prosecutors in San Mateo County, California recently convicted a man for driving under the influence of the herb kava, marking just the second such conviction in U.S. history. Kava, an herb used as a nutritional supplement to relieve anxiety, is often used to make tea. The herb is commonly used in ceremonies by the county's Pacific Islander community. The defendant had consumed three bowls of kava and was pulled over weaving between lanes. He was charged with DUI after he failed field sobriety tests measuring reflexes and visual alertness. Kava is not classified by FDA as a drug, but studies have found that large doses impair motor function and have anesthetizing effects. California law prohibits driving while impaired by any substance. The San Mateo County crime lab is working with the San

Francisco medical examiner to develop a kava equivalent for the blood-alcohol test used to convict drunk drivers. Officials are hoping to develop a test that will detect kava in the bloodstream and define the level that renders drivers too intoxicated to drive. Pacific Islanders in the community expressed alarm over the crackdown on kava. "The legal system is being used to restrict our traditions," said Chester Palesoo, head of the Pacific Islander Community Center. But officials said drinking kava in moderation should not affect rituals. "There's no law to say you can't have kava. But if you are going to drink enough to impair you, just don't go behind the wheel, take a 4,000 pound piece of metal and hurtle it down the road," said Peter Lynch, a San Mateo County deputy district attorney.

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"State tracking who needs flu shot, files price-gouging suit"
Associated Press (10/22/04) Susan Haigh
http://www.stamfordadvocate.com/news/local/state/hc-22013131.apds.m0661.bc-ct-flusoct22,0,704752.story?coll=hc-headlines-local-wire

Connecticut has filed a lawsuit against Florida-based pharmaceutical wholesaler Meds-Stat for alleged price gouging in connection with the influenza vaccine shortage. State Attorney General Richard Blumenthal said the company is illegally operating in Connecticut and charging up to \$900 per vial of flu vaccine, more than 10 times the standard market value. Prior to news of the vaccine shortage, Meds-Stat was selling flu vaccine for \$70-\$90 per vial of ten doses. "This is clear-cut unconscionable price gouging. A 10-fold increase, a 1,000 percent hike in prices, clearly crosses the line," he said. Attorneys general in Florida, Kansas, and Texas have also filed suit against the company. A Meds-Stat spokesman denied the accusations and said the company would "vigorously defend its action and is confident it will prevail on the merits of these cases." Meanwhile, Connecticut Governor M. Jodi Rell told residents there is no reason to panic about the flu vaccine shortage. "We are doing the best we can with the shortage that we have at hand. And I think that we are addressing, as quickly as possible, through all of the appropriate channels getting the vaccine to as many places as possible," she said.

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"State: Flu shots only for people at high-risk, doctors forbidden to give vaccine to others" The Asheville Citizen-Times (10/19/04) John Boyle www.citizen-times.com

North Carolina State Health Director Leah Devlin has sent letters to physicians and other practitioners across the state, notifying them that they can only give flu vaccine to those in a high-risk category. A provision of the North Carolina Administrative Code dealing with control measures for communicable diseases (10A NCAC 41A .0201) states that guidelines issued by CDC are automatically incorporated into the state's law. Most health professionals said the legal notification was expected. "It's unusual to have (the policy) change in mid-year, but it's just because of the situation this year that the CDC changed the guidelines," said Dr. Susan Mims, medical director at the Buncombe County Health Center. "When people come and ask for a shot and they're not in a high-risk category, they need to know that we're not just being mean when we say we can't give them one. We need to save the shots for high-risk people," she said. Several other jurisdictions have sent similar notices to health care professionals, including Michigan, Massachusetts, and Washington, D.C.

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"Flu shot shortage vexes state officials"

Stateline.org (10/22/4) Erin Madigan

http://www.stateline.org/stateline/?pa=story&sa=showStoryInfo&id=407266

The shortage of influenza vaccine has state health officials, governors, and attorneys general working to inventory, ration, coax, or order the distribution of vaccine to ensure that it gets to those who need it most. Several states have issued emergency orders to ration vaccine, including Michigan, California, D.C., Massachusetts, New Mexico, Oregon, South Carolina, Vermont, and Wisconsin. Other states, such as Maine, Minnesota, and North Dakota, are surveying health care facilities to get a count of how much vaccine they have on hand relative to their need. Vermont Governor James Douglas is seeking federal permission to import vaccine from Canada, while Illinois is seeking permission to import vaccine from Europe. "This year, every state is challenged with trying to figure out where vaccine is in their state," said Claire Hannan, executive director of the Association of Immunization Managers. At least four states are taking legal action over alleged price gouging, including Connecticut, Kansas, Kentucky, and North Carolina. Other jurisdictions are taking different steps, including a flu-shot vaccine lottery for high-risk patients in a county in New Jersey, and Arizona's call for a national vaccine summit.

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"Government scrambling to bring flu vaccine into U.S.; antivirals at the ready" Washington Fax (10/25/04) (subscription required) http://www.washingtonfax.com/

U.S. officials said last week they are in negotiations with influenza vaccine manufacturers in other countries to try to acquire additional doses of vaccine for the 2004-2005 flu season. At least 20 manufacturers produce the vaccine globally. Officials must now determine which companies have the type of influenza vaccine usable against northern hemisphere strains, according to Bruce Gellin, director of the HHS National Vaccine Program Office (NVPO). Gellin said if prospective suppliers do not have a U.S.- licensed product, a thorough review of their master file and an FDA inspection of their facilities would have to be completed to make sure the vaccine passes FDA scrutiny. Meanwhile, federal officials say they have antiviral drugs at the ready for use as preventatives or as therapeutic agents against influenza. CDC has seven million doses of antiviral drugs stockpiled and another 33 million doses are currently available, according to HHS Secretary Tommy Thompson. Officials said various federal agencies are working to speed up the manufacturing process for flu vaccine in the future, and to understand what companies need to make the vaccine business more viable.

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"Growing danger: Drugged driving; Movement afoot to pass laws" USA Today (10/22/04) Donna Leinward http://www.usatoday.com/printedition/news/20041022/1a cover22.art.htm

DUI charges against a driver involved in an auto crash can be readily proved in court through bloodalcohol test results. When crashes involve the use of drugs, however, a charge of driving under the influence of drugs can be much more difficult to prove. Most states have no legal standard for determining what level of drugs in a person's system renders them too impaired to drive. The lack of such standards makes it more difficult to try such cases. More than 1.5 million people were arrested for drunk driving last year. Public health and law enforcement officials estimate that as least as many people drove under the influence of drugs, though few are ever prosecuted. Now, some government and law enforcement officials are calling for a change. Congress is considering a proposal that would make the states' receipt of federal transportation money contingent on the adoption of "zero tolerance" drug laws. Such laws would make it a crime for people to drive with any amount of illicit drugs in their system. The bill, called the Drug Impaired Driving Enforcement Act of 2004, has passed both the House and Senate and is currently before a conference committee. Eleven states currently have such laws: Arizona, Georgia, Indiana, Illinois, Iowa, Michigan, Minnesota, Pennsylvania, Rhode Island, Utah, and Wisconsin. Nevada has a law that sets impairment guidelines for levels of drugs such as heroin, marijuana, cocaine, and methamphetamine. Five states are testing new roadside tests that use saliva to detect the presence of drugs.

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"Postexposure prophylaxis, isolation, and quarantine to control an import-associated measles outbreak -- Iowa, 2004"

Morbidity and Mortality Weekly Report (10/22/04) V. McKeever and others http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5341a3.htm

This report updates previously published information about a cluster of three measles cases in an "insular community" in Iowa in March 2004. The community had low measles vaccination rates. All three measles patients were placed in voluntary isolation and monitored by public health authorities. Two exposed health care workers were placed in quarantine. Seven exposed members of the insular community were also placed in quarantine after refusing postexposure immunizations. Because the seven were unwilling to comply with voluntary quarantine, they were served with involuntary home quarantine orders for up to two weeks. No known breaks in quarantine occurred and none of the seven acquired measles. No other cases of measles occurred. In an accompanying editorial note, the authors noted that quarantine, a centuries-old public health tool, has been used only rarely in the United States since the advent of antibiotics and vaccines. In the rare instances when quarantine has been used, it has been done under state law, although, in certain circumstances, the federal government may also detain persons for the control of communicable diseases. To be effective and acceptable, quarantine must be applied equally and fairly, balancing individual civil liberties with the collective needs of the public's health. Quarantine must be accompanied by appropriate due process measures (such as written notice and an opportunity to appeal the order), and education of the public about the need for quarantine.

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"Canada's vaccine plan may be model for U.S."
The Washington Post (10/25/04) David Brown
http://www.washingtonpost.com/wp-dyn/articles/A59493-2004Oct24.html

Some experts believe that the U.S. should borrow some ideas from the Canadian model for supplying influenza vaccine. Like the U.S., Canada has only two suppliers of influenza vaccine, and fluctuating public enthusiasm for flu shots. But in Canada, the public works ministry orders about 90% of the influenza vaccine the country uses each year. The vaccine manufacturers bid on long-term contracts for

the portion of the national supply they will produce. The public works ministry tells the manufacturers how much to make, based on the share they have won. The companies also make extra doses, to be sold in the private market operating outside of the national health system, or to the world market. But the majority of the vaccine is made without financial risk to the companies. HHS Secretary Tommy Thompson is among those who believe the U.S. government needs to guarantee a market for a specified number of flu vaccine doses each year. A guaranteed market would not have prevented the current flu vaccine shortage, but some say it might lure other companies back into the market, making the supply less vulnerable to disruption.

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"Influenza vaccine supply and international law" ASIL Insights (10/2004) David P. Fidler http://www.asil.org/insights/currinsight.htm

The current shortage of influenza vaccine raises several potential issues implicating international law, such as how to increase global vaccine supplies and how to respond to influenza epidemics or pandemics when vaccine supplies are inadequate. Many experts believe a coordinated global strategy is needed to increase the scale and stability of influenza vaccine production. Binding and non-binding agreements among nations are needed to construct such a global regime. The World Health Organization's proposed revision of the IHR would give WHO authority to issue recommendations with respect to public health emergencies of international concern. Countries that import and export vaccine could improve communication though non-binding memoranda of understanding or binding agreements. International cooperation could also include vaccine rationing among countries when shortages occur. The current shortage in the U.S. has brought the fragility of the influenza vaccine supply to the forefront. Both strong and weak countries are vulnerable to inadequacies in global vaccine production, and many countries are dangerously unprepared to face pandemic influenza.

BRIEFLY NOTED

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California: Fluoridation lawsuit dismissed "Judge tosses Escondido, Calif., fluoridation lawsuit" Knight Ridder (10/19/04) Teri Figueroa

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Illinois: State seeks approval to buy flu vaccine from abroad FDA promises quick review of flu plan Chicago Sun-Times (10/26/04) Jim Ritter http://www.suntimes.com/output/news/cst-nws-flu26.html

Iowa: Officials working on meth lab cleanup policies

"State works on guidelines to deal with former meth lab sites" Associated Press (10/25/04) http://www.woi-tv.com/Global/story.asp?S=2473556

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Missouri: Gov. signs executive order urging providers to follow flu guidelines "Health Department works to gauge scope of flu shot problem" Associated Press (10/25/04) Kelly Wiese www.kansascity.com (registration required)

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The Dallas Morning News (10/21/04) Roger Yu

http://www.dallasnews.com/sharedcontent/dws/dn/latestnews/stories/102104dntexflugouge.b97b8.html

National: Sen. Bayh touts federal Flu Protection Act "Bayh says proposed bill would help prevent flu vaccine shortage" Associated Press (10/21/04) http://www.indystar.com/articles/1/188134-6041-P.html

National: Vaccine delivery system fine-tuned "CDC refines flu vaccine message, works out allocation plan" American Medical News (11/01/04) Susan J. Landers http://www.ama-assn.org/amednews/2004/11/01/hlsb1101.htm

National: Chiron cautious about next year's vaccine supply "Chiron vaccine in doubt for 2005"

USA Today (10/21/04) Anita Manning
http://www.usatoday.com/news/health/2004-10-20-chiron-usat_x.htm

National: Draft news release indicates Chiron knew of problem "Chiron had prepared to withhold Fluvirin as early as late September" The Wall Street Journal (10/20/04) Pui-Wing Tam and Sarah Lueck http://online.wsj.com/article_print/0,,SB109820857444649465,00.html

National: National Synthetic Drugs Action Plan announced "Feds to push states on anti-drug plan"

USA Today (10/25/04) Donna Leinwand http://www.usatoday.com/news/nation/2004-10-25-feds-antidrugplan_x.htm

National: Some local health providers considering drastic measures "Officials differ on degree of flu crisis"

San Mateo County Times (10/20/04) Rebecca Vesely

http://www.sanmateocountytimes.com/Stories/0,1413,87%257E11268%257E2480740,00.html

PHL NEWS QUOTATION OF THE WEEK	
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"My message to those thinking about exploiting this crisis to rip-off health-care providers and vulnerable consumers is this: You're not going to get away with it in California."

-- Bill Lockyer, California Attorney General, commenting on recent reports of price-gouging amid a shortage of influenza vaccine. Lockyer's office can prosecute those offering the flu vaccine for sale at inflated prices, even if no sale is made, he said. California has subpoenaed drug wholesaler Nationwide Medical Surgical, Inc. as part of an investigation into alleged price gouging [see Briefly Noted item 1, above].

THE WEEKLY READING: NUMBER TEN

Each week for 26 weeks, the Weekly Reading provides *News* subscribers with a key reading in public health law. In each issue, we post a short description of the reading, a link, and a quiz question. The series is designed to provide a foundation for understanding public health law.

Reading Ten: *Benning v. State of Vermont* (1994). In this week's reading, we continue a bedrock theme in public health law, the tension between the rights of individuals and the power of government to take action necessary for the common good. This week's case was an attack on the Vermont motorcycle helmet law. The plaintiff, Benning, argued that he, not the Vermont state government, should have the power to decide what is necessary for his own personal safety. His arguments were conceptually similar to those presented by Hartog in last week's case, *State of Iowa v. Hartog*.

Click here for reading ten: http://www.phppo.cdc.gov/od/PHLP/docs/Benning.pdf.

Question on Reading Ten (the answer will be provided in next week's issue): In a 1969 case called *State v. Solomon*, the Vermont Supreme Court held that the state's motorcycle helmet law did not exceed the scope of the state's police power, and did not violate the Due Process Clause of the Fourteenth Amendment to the United States Constitution. This would seem to have foreclosed Benning's attack on the same helmet law 25 years later, because courts are loath to depart from their own precedents (a principle in the law called *stare decisis*, "to stand by that which is decided"). To get around this, Benning tried to distinguish his case from *Solomon*. How did he do this?

Answer from last week's reading. Question: Hartog argued that the Iowa seatbelt law was unconstitutional because it lay beyond the reach of the state's police power, which is defined as the legislature's broad, inherent power to pass laws that promote the public health, safety, and welfare. What was Hartog's principal argument in support of that claim and how did the Court answer it? Answer: Hartog argued that the purpose of the statute was to "protect the individual from his own folly and, consequently, such purpose has no relation to the public health, safety, or welfare." Hartog's argument implied that "the decision whether to wear a seat belt is a personal one affecting him only; therefore, he should be able to make that decision free of state interference."

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